

REMARKS

Reconsideration and withdrawal of the rejections of the present application are respectfully requested in view of the amendments and remarks presented herewith, which place the application into condition for allowance.

Status of the Claims and Formal Matters

Claims 1-15 are currently pending in this application. Claims 12-15 have been added to claim certain specific species. No new matter has been added by these amendments.

The amendments presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments are made simply to round out the scope of protection to which Applicants are entitled.

Rejections under 35 U.S.C. § 112, ¶ 1, 2

Claims 1-11 were rejected under 35 U.S.C. § 112, ¶ 1, because the compounds referred to in Table 1 allegedly did not appear to fall within the scope of the claims that require a C-terminal amidation. It was noted that without working examples of the present invention and given the unpredictability in the art, it would require “undue experimentation” for one of skill in the art, i.e., a skilled cardiologist attempting to treat a patient’s hyperlipidemia, to practice the claimed invention. These claims were further rejected under 35 U.S.C. § 112 ¶ 2 for failing to particularly point out and distinctly claim the subject matter of the present invention.

We respectfully request reconsideration of these rejections, because one of ordinary skill in the art would recognize that Claim 1 permits the sequences appearing within a larger peptide sequence, which could include the species found in Table 1.

Initially, in support of these claims, applicant states that the parallel application in Europe has been allowed. It is suggested that the Examiner review a number of attached documents related to that application. While obviously not binding on the U.S.P.T.O., as noted in these documents, the European Patent Office found the claims novel and inventive over the prior art, citing a reference to U.S. Patent No. 6,046,168 (International Preliminary Examination, PCT/KR2003/001017, Sept. 14, 2004). The European Examining Division provided notice that

it intended to grant a European patent (EPO Communication, Feb. 17, 2006). Applicant wishes to direct the Examiner to note that the claims presented to the European Patent Office are substantially similar, where it appears that it was understood by one of ordinary skill in the art that certain modifications would only be made where possible. For example, it would be known to this person that it was not possible to replace the "NH₂" group of Pro-Tyr-Val, because there is no "NH₂" group in the ring structure.


In addition, applicant asserts that despite the absence of working pharmaceutical composition examples, one of ordinary skill in the art, e.g., a skilled cardiologist, could easily select appropriate components, such as carriers, to make the pharmaceutical composition of claim 1, without undue experimentation. This was found to be true by the examiner in the European Patent Office, who would be similarly situated as one of ordinary skill in the art. Applicant reasserts that working examples outside of the experimental results reported does not appear to be required in this instance. Because there is no sufficient experimental data, the applicant has chosen not to claim a mixture of the claimed peptides.

CONCLUSION

By this Amendment, this application is believed to be in condition for allowance. Favorable reconsideration of the application, entry of the amendments, withdrawal of the rejections, and prompt issuance of the Notice of Allowance are, therefore, all earnestly solicited.

Respectfully submitted,
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